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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

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Additional inventors are being named on the — *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

DEVICE AND METHOD FOR SPINAL FUSION

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ENCLOSED APPLICATION PARTS (*check all that apply*)

☑ Specification *Number of Pages* 11 ☐ CD(s), Number

☑ Drawing(s) *Number of Sheets* 5 ☐ Other (specify)

☐ Application Data Sheet. See 37 CFR 1.76

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Respectfully submitted,

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

DEVICE AND METHOD FOR SPINAL FUSION

FIELD OF THE INVENTION

The present invention relates to the field of the orthopaedic fusion of vertebrae, especially as performed by the use of mechanical clamping devices for external fixation of neighboring vertebrae.

BACKGROUND OF THE INVENTION

Vertebral fusion is a common spinal surgical procedure, performed in order to overcome problems related to impaired mutual interaction between neighboring vertebrae. There are a number of indications requiring spinal fusion operations, including:

(i) traumatic fracture of the vertebral body;

(ii) degenerative disc or vertebral disease, such as disc herniation, instability of the facet joint, compressive radiculopathy;

(iii) following the failure of previous spinal surgery, or the removal of a disc;

(iv) chronic vertebral or disc infection;

(v) vertebral instability, such as in spondylolisis or spondylolystetis; and

(vi) following the removal of spinal tumors.

The technique involves the disablement of the relative motion between adjacent vertebrae to prevent compression during body movements and for stabilizing the spinal column. Spinal fusion is a very common procedure, with over 400,000 procedures performed annually in the USA alone.

Three methods are currently generally used for performing this procedure:

(a) Fixation of the rear of the vertebrae by means of hooks, two of which are generally used to hook onto the laminae on either side of the vertebrae, and connection between them by means of a metallic rod.

(b) Pedicle screw insertion into the body of the vertebra. This method involves the insertion of two screws per vertebra, on the left and right spinal pedicles. A rigid rod is inserted between holes in the screw head on either side of the vertebra, thus preventing motion between adjacent vertebra.

(c) Fixation of the front part of the vertebrae, either by means of screws inserted into the body of the vertebra, or by use of hollow threaded cages inserted into pre-drilled tracts between the vertebrae, and which are filled with bone graft material, which ultimately fuses with the vertebral bodies to consolidate the fusion.

Each of these prior art methods has its own specific disadvantages:

(a) Hook fixation - because of the comparative weakness of the holding power of the hooks, a larger number of vertebrae need to be fused to achieve acceptable results, than when using the other methods. This may lead to unnecessarily limited movement of the spine in the operated region, with consequent problems of mobility. Furthermore, what should be a comparatively simple operation and localized operation becomes much more extensive, with concomitant increase in blood loss, time under anesthesia, and the need for an external brace for some time after the operation. Failure of the hooks to hold well may cause them to move during the healing period.

(b) Pedicle screwing - the insertion of the pedicle screw is generally a difficult, error prone and time consuming procedure. The surgeon must determine the entry point and the trajectory of the screw holes from X-ray fluoroscopic images taken from several angles, and this requires expertise and experience, and a well-trained operating room team. Furthermore, the method results in a high level of X-ray exposure to the surgeon and staff. The following problems can arise during this procedure:

(i) Breakage of the pedicle due to a misdirected drill, or poor drilling technique.

(ii) Penetration of the spinal cord, with resultant nerve damage.

(iii) Damage to neighboring nerve roots, causing pain and nerve damage.

(iv) Penetration of the abdominal cavity, with the resultant danger of damage to major blood vessels and hemorrhaging.

(v) Part of the upper tip of the facet joint often needs to be removed to provide room for the pedicle screw head.

A number of clinical studies have reported 10 to 40% misplaced screws, which is defined as a screw more than 2 mm away from the intended ideal position. It has been reported by R.W. Gaines in the article "The Use of Pedicle Screw Internal Fixation for Spinal Disorders", Journal of Joint and Bone Surgery, Vol. 82-A, No. 10, 2000, that about 3% of misplaced screws are more than 5 mm away from their planned position, almost inevitably causing nerve damage. Insertion of pedicle screws in the thoracic and cervical vertebrae is even riskier, because of the compact and delicate structure of the spine in these regions. For this reason, few experienced surgeons perform spinal fusion by this means at these levels, and in the USA, the procedure is not even FDA authorized for these regions.

(c) Fusion cage - in order to drill the necessary tracts for inserting the cages, or the holes for inserting the screws, this procedure requires one of two major surgical procedures. Either access is needed to the front of the spine through the abdomen or thoracic cavity, with its concomitant possibilities of complications, or access to the vertebrae from the rear, in which case a wide laminectomy procedure must be performed, and displacement of the entire dura matter in the region of the cage insertion.

Furthermore, in all of the methods, there are the general difficulties relating to surgery on the vertebral column, include micro-movement of the

vertebral column during the operation, the inherently small target objects of the procedure such as the pedicles, and delicate nerve tissue close to the operation region.

In the light of the above-mentioned disadvantages of the prior art methods, there therefore exists a need for a method of performing spinal fusion operations which provides less likelihood of complications and damage to the patient, especially to the spinal cord or nerves emanating therefrom, or to adjacent blood vessels, which should be simple to perform without requiring a high level of surgeon skill, which will not cause catastrophic damage in the event of a poorly executed procedure, which is short and requires minimal x-radiation exposure, and which utilizes simple instruments and therefore, does not require a highly skilled O.R. team.

The disclosures of each of the publications mentioned in this section and in other sections of the specification, are hereby incorporated by reference, each in its entirety.

SUMMARY OF THE INVENTION

The present invention seeks to provide a new device for use in performing vertebral fusion in a simple, safe and speedy manner, and use of which overcomes many of the above-mentioned disadvantages of the prior art methods.

There is thus provided in accordance with a preferred embodiment of the present invention, a vertebral fusion clamping device element, preferably of a metallic material, having a three-dimensional curved profile, shaped approximately like a miniature helmet with a long, turned-up tail at its lower end, shaped like the neck guard of the helmet, such that the element approximately matches the curvature of the top end of the pedicle and its adjacent features, the facet joint and the transverse process, and sits snuggly in that position. The top inside hollow of the element fits over the top end of the facet joint, and the lower half of the tail sits on the top end of the pedicle, while the turned-up very end of

the tail fits over the beginning of the transverse process. The element has two fixing holes, one near the bottom of the tail, at the saddle point of the element, and the other at the top of the outer surface of the top hollow. The first hole is adapted to receive a screw to be inserted into the top end of the pedicle, close to its join line with the base of the transverse process, and the second hole is adapted to receive a screw to be inserted into the region of the top of the facet joint. However, unlike the prior art pedicle screw, which is long and is driven straight down the pedicle into the vertebra body, the screws of the present invention are short and thin, and angled such that they are inclined inwards towards each other, and are inserted only into the top ends of their respective bone bases. Since the bone structure of the top end of the pedicle is dense (cortical bone), the two inclined screws hold the element firmly and snuggly in its position, despite their short length. If necessary, the region of the bone structure on which the element sits is prepared preferably by means of an instrument, so that it has a profile similar to that of the inside of the element. The metallic element preferably has an attachment threaded rod between the two screw holes, in or near the top of the outer surface of the top hollow, onto which the vertebral clamping rods or plate are designed to be screwed. The upper end of the element preferably has a lip which is designed to fit into the facet joint, and the lower end of the element preferably has curved lateral extremities which grip the upper end of the pedicle and the base of the facet joint, such that when it is screwed into place, the element is firmly seated.

Use of the device of the present invention has a number of significant advantages over the prior art methods of performing spinal fusion. Firstly, the short drilling length of the screw holes reduces the likelihood of damage to the spinal cord, or any other adjacent feature, such as nerve ends or blood vessels. Furthermore, the short drilling length, the thinner screw and the drilling into dense cortical bone regions of the pedicle, means that there is little danger of breakage of the pedicle. Additionally, the use of two inclined screws inserted into cortical bone, despite their short length and smaller diameter, provides attachment

strength which is as adequate for the required task as that of the prior art use of single pedicle screws on each side. Because of the reduced danger of complications, and the simple physical procedure, the operation can even be performed by less experienced surgeons. Furthermore, the greater simplicity and safety of the use of the device of the present invention may make its use more acceptable for application to spinal fusion in the upper parts of the back, which has been hitherto more rarely performed, if at all allowable by the regulatory authorities. Finally, the reduced duration of the operation, typically down to half of that for a similar operation performed using prior art methods, and the reduced radiation exposure, make the use of the device of the present invention significantly safer to the patient.

An operation routine for performing spinal fusing procedure, according to a preferred method of the present invention, typically comprises the following steps. The patient is anesthetized, the spinal region where the fusion is to be performed is exposed, and the muscles detached from the various parts of the vertebrae to be treated, as in a normal spinal operation. After preparation of the site on which the vertebral fusion clamping device element is to sit, The vertebral fusion clamping device element is inserted into position and the two self-tapping fixing screws are driven into the outer cortical bone. Since these screws are of comparatively small diameter, there is generally no need to drill a pilot hole, other than a very fine insertion starting position, if preferred. This feature is one of the important differences between the procedure of the present invention, and the prior art pedicle screw insertion procedure, which generally requires a comparatively large pilot hole to be drilled, with the resulting potential dangers mentioned above. The vertebral clamping rods or plates are attached to fuse the chosen vertebrae together, and the subject's back is surgically closed again.

There is also provided in accordance with another preferred embodiment of the present invention, a vertebral fusion clamping device element, comprising a rigid shell structure having a three-dimensional curved inner profile, the profile being such that the element is adapted to generally match the outer profile of the

top end of the pedicle and its adjacent facet joint and transverse process, in a vertebra to be fused of a subject. In the above described element, there may be at least two holes for attachment of the element to the vertebra, the first one being such that when the element is positioned on the vertebra, the first hole is disposed opposite the top of the pedicle, and the second hole being such that it is disposed opposite the top of the facet joint. Furthermore, in the above-described element, the holes are preferably positioned in the surface of the rigid shell structure such that their axes are inclined towards each other. Additionally, the element also preferably comprises a threaded rod for fixing a connecting member between vertebral fusion clamping device elements mounted on adjacent vertebrae.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Figs.1 and 2 respectively illustrate schematic cross-sectional and lateral views of a prior art vertebral fusion using the pedicle screw procedure;

Fig. 3 schematically illustrates a frontal view of a prior art vertebral fusion using the threaded fusion cage procedure;

Figs. 4A to 4E illustrate schematically views of a vertebral fusion clamping device element, constructed and operative according to a preferred embodiment of the present invention, the views being taken from different directions to illustrate the structure of the element;

Figs. 5A to 5E illustrate schematically the various views of the vertebral fusion clamping device element of Figs. 4A to 4E, but without the screws inserted, to show the placement of the screw holes; and

Fig. 6 is a schematic cross-sectional illustration of a vertebra with the vertebral fusion element of the present invention fitted in its predetermined

position over the pedicle, the top of the facet joint and the base of the transverse process.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Figs. 1 and 2, which schematically illustrate cross-sectional and lateral views of a prior art vertebral fusion using the pedicle screw procedure. The drawings show the various parts of the vertebrae, including the body of the vertebra 10, the pedicle 12, the spinal cord 14, the facet joint 16, the transverse process 18, the spinal process 20 and the lamina 22. The pedicle screws 24 are seen to be inserted into the narrow pedicle, such that deviation from the planned insertion path could result in breakage of the pedicle. Furthermore, the screw holes run very close to the spinal cord 14.

The lateral view of Fig. 2 illustrates how the fixing rods 26 are attached under the prior art screw heads to render the fusion of the vertebrae.

Reference is now made to Fig. 3, which schematically illustrates a frontal views of a prior art vertebral fusion using the threaded fusion cage procedure. The fusion cages 30 with bone graft material therein 32 are shown inserted between two vertebrae bodies 34, 36, from the front of the spine, with the disadvantages of this method.

Reference is now made to Figs. 4A to 4E, which illustrate schematically various views of a vertebral fusion clamping device element 50, constructed and operative according to a preferred embodiment of the present invention. The various views in Figs. 4A to 4E are taken respectively from the left side (Fig.4A), from the rear side (Fig.4B), from the front side (Fig.4C), from above (Fig.4D) and from the right side (Fig.4E). The characteristic parts of the vertebral fusion clamping device visible in some or all of these views are the upper 52 and lower 54 fixing screws, the threaded rod 56 for attachment of the fusion plate or rods, the upper cover 58 for fitting over the top of the facet joint, and the lower tail end 59 for fitting over the top of the pedicle near its join with the base of the

transverse process. In Fig. 4E, the inwardly inclined angle of the fixing screws 52, 54, is shown clearly, whereby the vector addition of the holding force of the two inclined screws is directed down the pedicle direction, thereby holding the clamping device element of the present invention firmly on the pedicle, in a similar manner to that of the prior art pedicle screw method, but with smaller screws and reduced inherent dangers of complications.

Reference is now made to Figs. 5A to 5E, which illustrate schematically various views of the vertebral fusion clamping device of Figs. 4A to 4E, but without the screws inserted, to show the placement of the screw holes.

Reference is now made to Fig. 6, which shows a schematic cross-sectional view of a vertebra 60 with the vertebral fusion clamping device element 50 of the present invention fitted in its predetermined position over the top end of the pedicle 12, the top of the facet joint 16 and the base of the transverse process 18. The threaded rod 56 to which the fusion plate or rods are attached is visible, together with the upper 52 and lower screws.

Reference is now made to Fig. 7, which is a photograph of a model of the spine, with the vertebral fusion clamping device element of the present invention installed on one vertebra, to provide a rendering of the way in which the element sits three dimensionally in its position on the vertebra.

Though the vertebral fusion clamping device element of the present invention has been described hereinabove as operating independently, it is to be understood that it can also be used as an additional support device for the cage procedure described in the prior art, to assist in support until the bone grafts within the cage have taken.

It is appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of various features described hereinabove as well as variations and modifications thereto which would occur to a person of skill in the art upon reading the above description and which are not in the prior art.

CLAIMS

We claim:

1. A vertebral fusion clamping device element, comprising a rigid shell structure having a three-dimensional curved inner profile, said profile being such that said element is adapted to generally match the outer profile of the top end of the pedicle and its adjacent facet joint and transverse process in a vertebra to be fused of a subject.

2. The element of claim 1 and wherein said element also defines at least two holes for attachment of said element to said vertebra, a first one of said holes being such that when said element is positioned on said vertebra, said first hole is disposed opposite the top of said pedicle, and a second one of said holes being such that when said element is positioned on said vertebra, said second hole is disposed opposite the top of said facet joint.

3. The element of claim 2 and wherein said holes are positioned in the surface of said rigid shell structure such that their axes are inclined towards each other.

4. The element of any of claims 1 to 3 and also comprising a threaded rod for fixing a connecting member between vertebral fusion clamping device elements mounted on adjacent vertebrae.

ABSTRACT

A vertebral fusion clamping device element, having a three-dimensional curved profile, shaped to match the curvature of the top outer end of the pedicle and its adjacent features, the facet joint and the transverse process. The element has two fixing holes, one near the bottom and the other near the top of the element. The first hole is for a screw to be inserted into the top end of the pedicle, close to its join line with the base of the transverse process, and the second hole is for a screw to be inserted into the region of the top of the facet joint. The screws of the present invention are shorter and of smaller diameter than those of previously used pedicle screws and are angled such that they are inclined inwards towards each other, and are inserted only into the top ends of their respective bone bases. The element is thus installed with greatly reduced danger of damage to the spinal cord or of breakage of the pedicle, in comparison with previously used pedicle screw fusion procedures.

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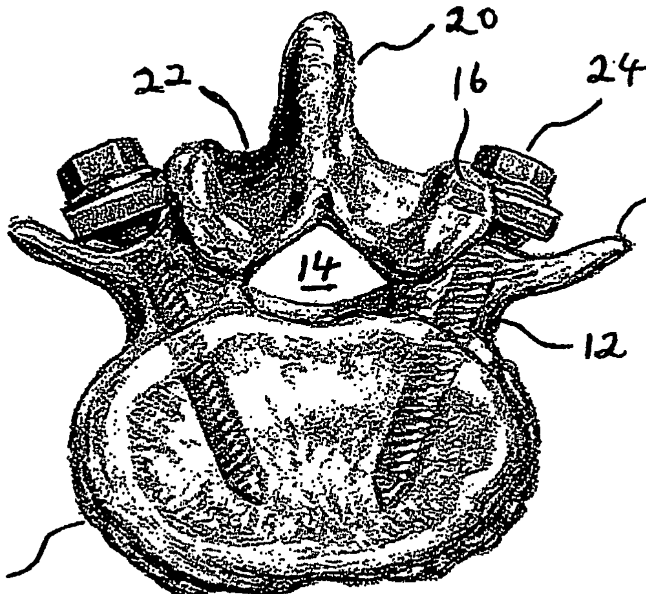


Fig. 1.
(Prior Art)

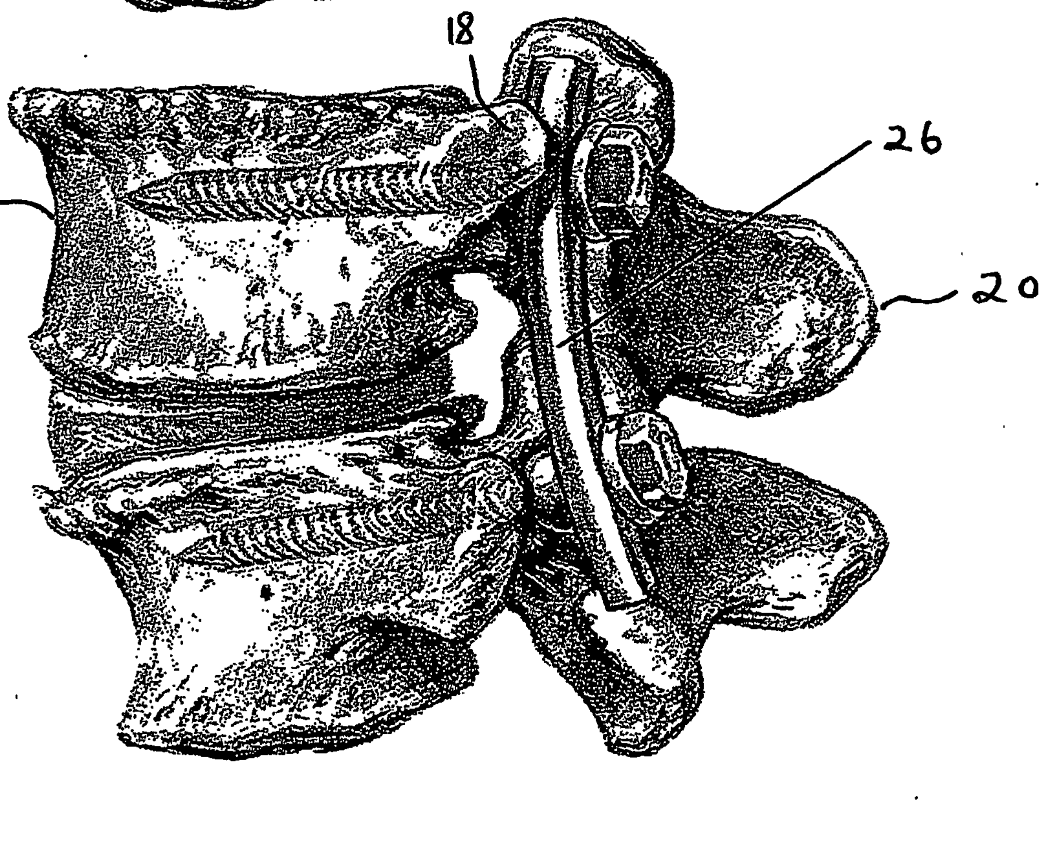


Fig 2.
(Prior Art)

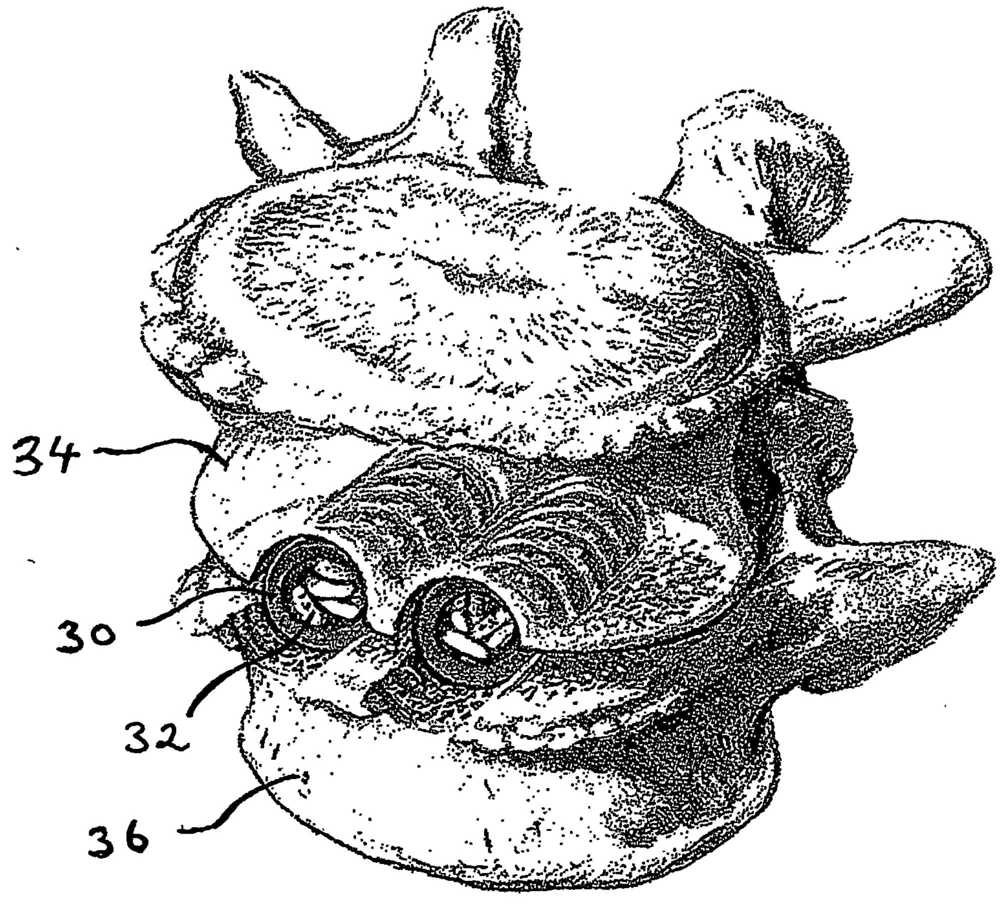


Fig. 3
(Prior Art)

Fig. 4A

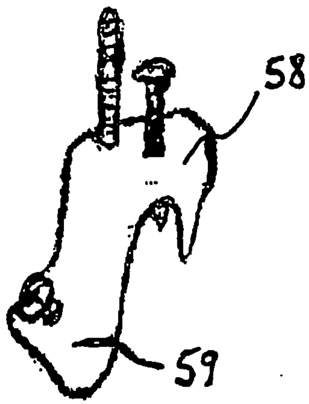
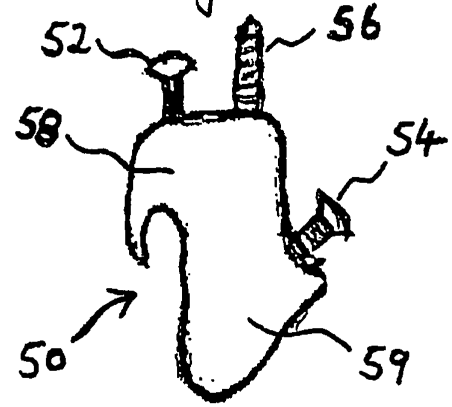


Fig. 4B

Fig. 4C

Fig. 4D

Fig. 4E



VIEW FROM → LEFT

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RIGHT

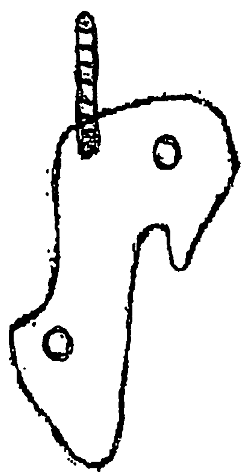

Fig. 5A

Fig. 5B

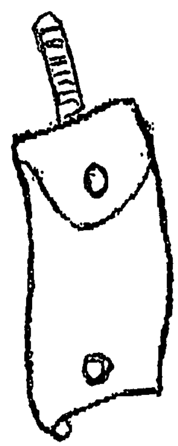

Fig. 5C

Fig. 5D

Fig. 5E

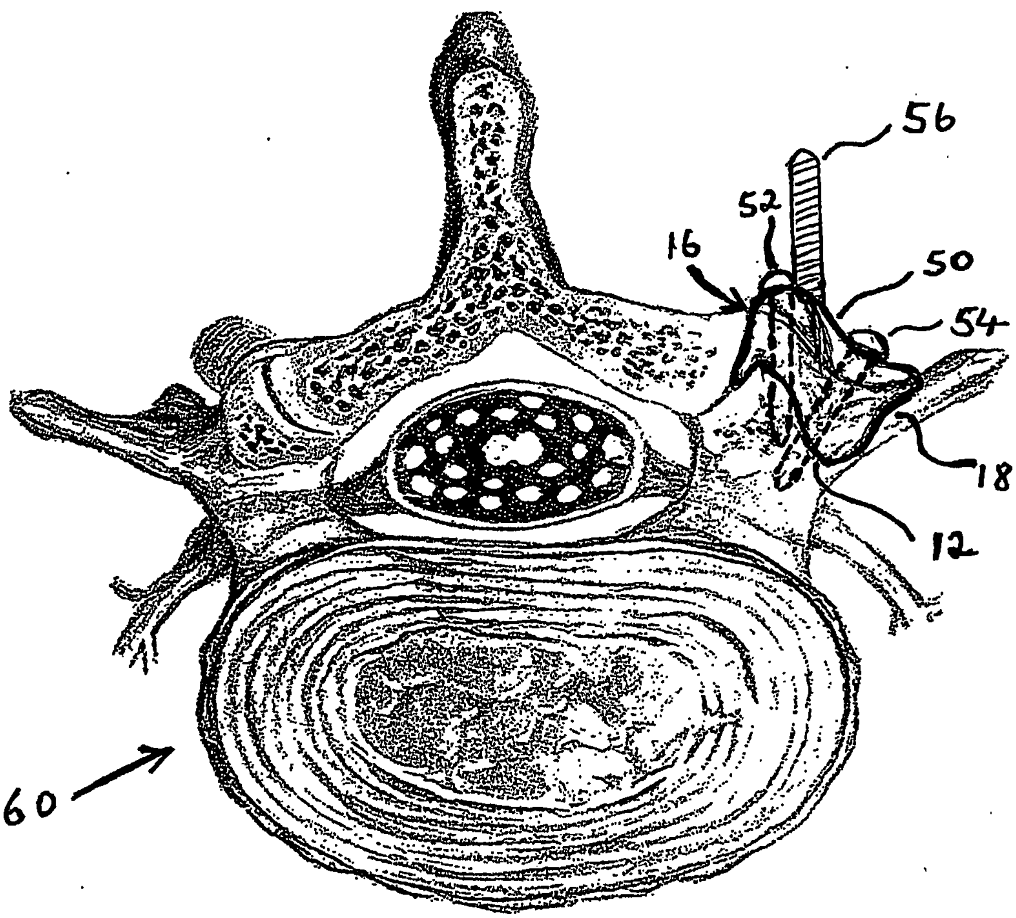

Fig. 6


Fig 7